EXHIBIT H

Randomized Trial of Tension-Free Vaginal Tape and Tension-Free Vaginal Tape-Obturator for Urodynamic Stress Incontinence in Women

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Abbreviations and Acronyms

ICIQ-SF = International Consultation on Incontinence Questionnaire-Short Form

KHQ = King's Healthcare Questionnaire

SUI = stress UI

TVT = tension-free vaginal tape

TVT-O = tension-free vaginal tape-obturator

UI = urinary incontinence

USI = urodynamic SUI

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Study received ethical approval at each site.

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Purpose: We compared the efficacy and complications of tension-free vaginal tape and tension-free vaginal tape-obturator.

Materials and Methods: Women with pure urodynamic stress incontinence undergoing only primary continence surgery were randomized to tension-free vaginal tape or tension-free vaginal tape-obturator at 2 centers between March 2005 and March 2007. Primary outcome was objective cure rate at 6 months, defined by a 24-hour pad test of less than 5 gm. Secondary outcomes were the subjective cure rate on the Patient Global Impression of Improvement, quality of life on the King's Healthcare Questionnaire and symptom severity scores on the International Consultation on Incontinence Questionnaire.

Results: A total of 127 women were recruited. The study was stopped early due to excess leg pain in the tension-free vaginal tape-obturator group. Of the women 66 were randomized to tension-free vaginal tape and 61 were randomized to tension-free vaginal tape-obturator. Analysis was done by intent to treat. The objective and subjective cure rate at 6 months for tension-free vaginal tape vs tension-free vaginal tape-obturator was 69.7% vs 72.1% and 72.7% vs 67.2% ($p = 0.76$ and 0.49, respectively). Cure rates at 1 year were similar but loss to followup was high. Objective and subjective cure rates at 1 year for tension-free vaginal tape vs tension-free vaginal tape-obturator were 50% vs 41% and 53% vs 42.6% ($p = 0.31$ and 0.24, respectively). More women complained of leg pain after receiving a tension-free vaginal tape-obturator (26.4% vs 1.7%, $p = 0.0001$). The incidence of perioperative complications was low and similar between the groups. Time to discharge home and time to normal activity were not significantly different.

Conclusions: Short-term cure rates at 6 months were similar. Tension-free vaginal tape-obturator caused more transient leg pain. Each procedure achieved a high cure rate and a low complication rate.

Key Words: ureter; urinary incontinence, stress; suburethral slings; female; complications

URINARY incontinence is experienced by 25% of women.[1] The lifetime risk of undergoing a single operation for UI or pelvic organ prolapse is 11%.[2] SUI, the most prevalent type of UI,[1] is the involuntary leakage of urine due to increased abdominal pressure during exertion, sneezing or coughing.[3] The most common surgical procedure for SUI is TVT™ placement.[4] TVT has less postoperative morbidity than open Burch colposuspension[5] and is equally effec-

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tive at 5 years with an 81% cure rate.[6] It is currently considered the first line surgical option for SUI. Complications arising from retropubic tape placement include bladder perforation and rarely bowel or large vessel injury. Transobturator mid urethral tapes aim to lessen these risks by passing the tape through the obturator foramen. The technique was first described by Delorme, who reported a 90.6% cure rate.[7]

While a large body of data exist on TVT efficacy and complications, there are more sparse comparative data on retropubic and transobturator tapes.[8–10] We evaluated the effectiveness and complications of TVT and TVT-O for USI in women. TVT-O uses an inside out trocar pass through the obturator foramen.[11] The 2 devices use the same macroporous monofilament polypropylene mesh.

MATERIALS AND METHODS

Participants were recruited from 2 hospitals. Ethical approval for the study was obtained at each site and written informed consent was obtained from all participants. Only women with USI as the only diagnosis without previous continence surgery were approached for the trial. Women with detrusor overactivity and USI were not approached. Women with uterovaginal prolapse greater than stage I based on the Pelvic Organ Prolapse Quantification staging system[12] were excluded from analysis, as were women with voiding dysfunction, defined as maximum flow rate less than 15 ml per second or post-void residual urine volume 100 ml or greater.

Randomization was done by a computer generated list randomized in blocks to ensure balanced allocation. Block size was randomized between 4 and 10. Numbered opaque envelopes were opened immediately before surgery.

The 2 procedures were performed using local anesthesia and intravenous sedation. In the original description of the TVT-O procedure by de Leval and Waltregny general anesthesia was used.[11] In our study TVT-O was done using local anesthesia and sedation so as not to bias outcomes, such as postoperative pain, postoperative stay and operative time, compared to those of TVT.

Intraoperative cystoscopy with a 70-degree cystoscope was performed in all cases, including twice after each trocar pass during the TVT procedure and once at the end of the TVT-O procedure. Urethral catheterization was routinely used in all cases intraoperatively but not postoperatively.

Intraoperatively 120 mg gentamicin were given intravenously in all cases. At the end of the procedure 100 mg diclofenac were given rectally. TVT and TVT-O were performed as originally described by Ulmsten et al,[4] and de Leval and Waltregny.[11] Cough testing was done intraoperatively to guide tape tension in TVT procedures only since de Leval and Waltregny did not describe using the cough test. We recorded intraoperative and immediate postoperative complications, operative time and time to discharge home. Pain was assessed using a visual analog score 2 hours after surgery and at 1 week (returned by mail).

The primary outcome measure was the cure rate 6 months postoperatively based on a 24-hour pad test with cure defined as a test result of less than 5 gm. The subjective cure rate was assessed using the patient rated 7-point (very much worse to very much better) Patient Global Impression of Improvement scale[13] 6 months after surgery. Participants were considered cured if they were very much better. Participants also completed the KHQ[14] and ICIQ-SF[15] questionnaires at baseline and 6 months to evaluate changes in disease specific quality of life and symptom severity. A 3-day urinary diary was also completed at baseline and 6 months to assess the number of leakage episodes. Similar outcome measures were also obtained 1 year after surgery.

Participants and assessors were not blinded to the treatment received. Blinding would have proved difficult since the procedures use different incisions that are easily distinguishable by patient and assessor. We thought that this would not introduce significant bias since efficacy was also assessed using objective outcome measures. Participants were reviewed and examined 3 and 6 months postoperatively to assess problems and tape erosion by a nurse or the operating surgeon. Postoperative problems were recorded at the 3-month visit.

Analysis was done by intent to treat with patients lost to followup considered treatment failures for objective and subjective outcomes. We also performed per protocol analysis at 6 and 12 months including only data on women who completed each followup visit. Data are reported as the mean ± SD, median with range and number with percent. Categorical data between the TVT and TVT-O groups were analyzed using the chi-square or Fisher exact test. Continuous data were compared using the Mann-Whitney U or independent samples t test depending on data normality. Preoperative and postoperative paired data were compared using the paired sample t or Wilcoxon signed rank test. Fisher's exact test was used to compare proportions. Significance was considered at 5%. Using a 65% objective cure rate for TVT[5] 100 participants were required per arm to detect a 20% difference in the cure rate with 80% power.

No formal data monitoring committee was convened for this trial but the investigators met as a steering group periodically to review recruitment and safety data. No formal interim analyses were planned.

RESULTS

The study recruited between February 2005 and September 2007. The figure shows patient recruitment and allocation. The 127 participants were randomized to TVT (66) and TVT-O (61). All patients underwent the allocated surgery.

During recruitment a few studies were published showing similar cure rates for the 2 procedures but a high incidence of leg pain in patients after receiving a transobturator tape.[16–18] After discussing these data at an investigator meeting we decided to stop recruitment before the full calculated sample was recruited since it was deemed that clinical equipoise had been lost. We believed that it was no longer ethical to randomize women to the TVT-O

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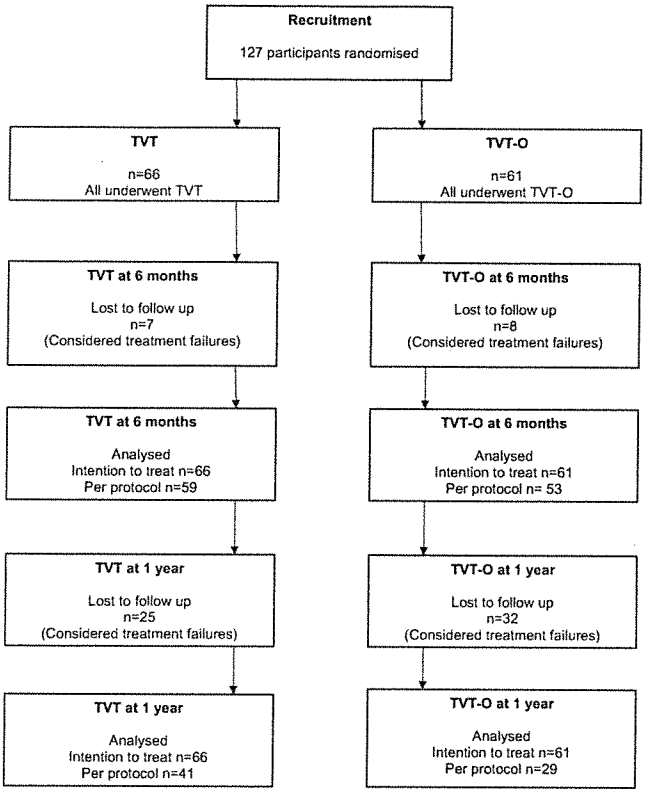

Study flowchart

arm in light of these published studies but data on women already recruited would be of value in future systematic reviews and meta-analyses.

Baseline characteristics were not significantly different between the TVT and TVT-O groups (table 1). TVT insertion was slightly more rapid than TVT-O insertion and caused less pain in the immediate postoperative period (table 1). There were no other significant differences in recovery or complications. One patient in the TVT group was returned to the operating room due to vaginal hemorrhage after surgery. Bleeding was due to a vessel along the edge of the vaginal incision, which was repaired vaginally. One patient in the TVT-O group had excessive intraoperative vaginal bleeding, which required compression and vaginal packing. Neither woman required blood transfusion. All erosion in the 2 groups was along the vaginal incision and detected at 3-month followup. Erosion in the TVT group developed in the patient who was returned to the operating room due to hemorrhage. All cases of erosion were managed surgically by mobilizing and reclosing the vagina over the erosion. Erosion in 1 TVT case failed to heal even after repeat closure and the tape was eventually excised.

At 6 months 7 patients in the TVT arm and 8 in the TVT-O arm were lost to followup and were considered treatment failures. The number of women lost to followup was higher than expected. This may have been due to the numerous outcome measures that they were required to complete, which they may have found burdensome.

By intent to treat the 6-month objective cure rate was 69.7% for TVT and 72.1% for TVT-O, representing a 2.4% difference (95% CI −13.3–17.8). By intent to treat the 6-month subjective cure rate was 72.7% for TVT and 67.2% for TVT-O, representing a 5.5% difference (95% CI −10.2–21.1, table 2). Table 2 shows 6-month objective and subjective cure rates after excluding losses to followup, per protocol analysis. Outcomes 1 year after surgery are also reported but the number of participants lost to followup increased substantially at 1 year, including 25 and 32 for TVT and TVT-O, respectively. One-year objective and subjective cure rates by intent to treat and per protocol analysis were similar for TVT and TVT-O (table 2). Other outcome measures of efficacy between the groups were similar at 6 months and 1 year (table 3). In the TVT and TVT-O groups mid urethral tape insertion resulted in significant improvement in quality of life, symptom severity and pad use (table 4).

Data revealed a large difference in the incidence of leg pain at followup, including 1.7% for TVT vs 26.4% for TVT-O, representing a 24.7% difference (95% CI 12.1–37.4).

DISCUSSION

TVT and TVT-O were equally effective based on objective and subjective cure rates. Porena et al reported similar objective cure rates of 77.3% for transobturator tape and 71.4% for TVT in a recent randomized trial.[19] The similar cure rates in our study are also in keeping with a large systematic review and meta-analysis by Sung et al.[20] The proportion of women reporting complete continence (no leakage) on the more rigorous outcome measure ICIQ-SF was approximately 50% in each group. This is consistent with the complete continence rate in other randomized trials.[5,21] Table 2 lists objective and subjective cure rates at 1 year. The main limitation of the 1-year cure rate was the high number of participants lost to followup, including 25 for TVT and 32 for TVT-O. Intent to treat analysis would explain the lower cure rates at 1 year since all losses to followup were classed as treatment failures. However, the 1-year cure rates in the TVT and TVT-O groups were similar. Although per protocol analysis was limited by numbers, it provided a reassuringly high cure rate for each procedure.

TVT-O took significantly longer to perform but the actual difference in duration was small (median 20 vs 22 minutes) and not clinically relevant. Other groups reported shorter operative time for TVT-O,

Table 1. *Baseline characteristics, operative data and complications*

	No. Pts	TVT	No. Pts	TVT-O	p Value	
Mean ± SD age	66	52.4 ± 11.8	61	50.9 ± 11.4	0.46	(independent samples t test)
Median kg/m^2 body mass index (range)	66	27 (21–37)	61	29 (21–50)	0.08	(Mann-Whitney U test)
Median parity (range)	66	2 (0–8)	61	2 (0–8)	0.15	(Mann-Whitney U test)
No. previous hysterectomy (%)	66	17 (25.8)	61	17 (27.9)		
No. premenopause (%)	66	25 (37.9)	61	25 (41)	0.83	(chi-square test)
No. postmenopause (%)	66	24 (36.4)	61	19 (31.1)		
No. previous prolapse surgery (%)	66	3 (4.5)	61	0	0.25	(Fisher's exact test)
Median gm pad test (range)	66	39 (1–513)	61	27 (1–367)	0.61	(Mann-Whitney U test)
Median KHQ score (range)	66	384 (122–814)	61	399 (106–814)	0.42	(Mann-Whitney U test)
Median ICIQ-SF score (range)	66	15 (7–21)	61	14 (3–21)	0.58	(Mann-Whitney U test)
Median No. diary leakage episodes (range)	52	3 (0–13)	46	3 (0–18)	0.48	(Mann-Whitney U test)
Median mins operative time (range)	66	20 (15–30)	61	22 (17–36)	0.02	(Mann-Whitney U test)
Median ml blood loss (range)	66	50 (20–200)	61	50 (20–400)	0.97	(Mann-Whitney U test)
Median cm visual analog scale score (range):						
2 Hrs	65	1 (0–7.5)	61	2 (0–8)	0.005	(Mann-Whitney U test)
1 Wk	53	1 (0–8.5)	52	1.5 (0–8.5)	0.26	(Mann-Whitney U test)
Median days discharge (range)	66	0 (0–1)	61	0 (0–1)	0.90	(Mann-Whitney U test)
Median days return to normal activity (range)	59	14 (1–90)	48	14 (0–60)	0.58	(Mann-Whitney U test)
No. hemorrhage (%)	66	1 (1.6)	61	1 (1.5)	0.95	(Fisher's exact test)
No. intermittent self-catheterization (%)	66	3 (4.5)	61	1 (1.6)	0.62	(Fisher's exact test)
No. bladder perforation (%)	66	0	61	0		
No. vaginal injury (%)	66	0	61	3 (4.9)	0.12	(Fisher's exact test)
No. leg pain (%)	59	1 (1.7)	53	14 (26.4)	0.0001	(Fisher's exact test)
No. de novo/worsening overactive bladder (%)	59	3 (5.1)	53	6 (11.3)	0.30	(Fisher's exact test)
No. vaginal tape erosion (%)	57	3 (5.3)	50	1 (2)	0.43	(Fisher's exact test)

which may be explained by differences in the type of anesthesia (regional or general compared with local anesthesia) and whether cystoscopy was done.[22,23] A recent study in which local anesthesia and intravenous sedation were used, as in our series, showed similar operative times for TVT and TVT-O.[24]

In our study the TVT-O group experienced a higher level of pain 2 hours postoperatively, although this did not prolong time to discharge home. At 1 week the discomfort experienced by each group was similar and time to return to normal activity was also the same. Laurikainen et al reported significantly increased opiate analgesic use postoperatively after TVT-O compared with TVT and longer time to hospital discharge.[24] This is not a consistent finding with another study reporting significantly higher postoperative pain in the TVT group.[23] This discrepancy may again be due to the different anesthesia used in each study.

The incidence of perioperative complications was similar in the 2 groups but pooled data suggest that the transobturator route results in significantly less bladder injury than that with TVT.[18] However, as the risk is still present we recommend cystoscopy for all transobturator procedures. The more horizontal support of the transobturator tape is also thought to make postoperative voiding dysfunction less likely. In a systematic review Latthe et al reported

Table 2. *Objective and subjective cure rates at 6 months and 1 year*

	No. Pts	No. TVT (%)	No. Pts	No. TVT-O (%)	p Value (chi-square test)
		Intent to treat analysis			
6 Mos cure:	66		61		
Objective		46 (69.7)		44 (72.1)	0.76
Subjective		48 (72.7)		41 (67.2)	0.49
1 Yr cure:	66		61		
Objective		33 (50)		25 (41)	0.31
Subjective		35 (53)		26 (42.6)	0.24
		Per protocol analysis			
6 Mos cure:	59		53		
Objective		46 (78)		44 (83)	0.50
Subjective		48 (81.4)		41 (77.4)	0.60
1 Yr cure:	41		29		
Objective		33 (80.5)		25 (86.2)	0.53
Subjective		35 (85.4)		26 (89.7)	0.59

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Table 3. *Efficacy outcome measures at 6 months and 1 year*

	No. Pts	TVT	No. Pts	TVT-O	p Value (chi-square test)
6 Mos:					
No. ICIQ-SF no leakage (%)	57	26 (45.6)	47	27 (57.4)	0.28 (chi-square test)
Median KHQ score (range)	57	58 (0–647)	49	58 (0–825)	0.82 (Mann-Whitney U test)
Median ICIQ-SF score (range)	57	1 (0–18)	47	0 (0–20)	0.72 (Mann-Whitney U test)
Median gm pad test (range)	59	1 (0–84)	53	1.5 (0–135)	0.78 (Mann-Whitney U test)
Median No. diary leakage episodes (range)	51	0 (0–8)	47	0 (0–10)	0.49 (Mann-Whitney U test)
1 Yr:					
No. ICIQ-SF no leakage (%)	37	13 (35.1)	27	15 (55.6%)	0.10 (chi-square test)
Median KHQ score (range)	37	50 (0–510)	27	61 (0–748)	0.82 (Mann-Whitney U test)
Median ICIQ-SF score (range)	37	4 (0–16)	27	0 (0–11)	0.19 (Mann-Whitney U test)
Median gm pad test (range)	41	1.8 (0–90.8)	29	0 (0–142)	0.91 (Mann-Whitney U test)
Median No. diary leakage episodes (range)	36	0 (0–6)	26	0 (0–9)	0.23 (Mann-Whitney U test)

significantly less risk of difficult voiding after transobturator tape placement (OR 0.55, 95% CI 0.31–0.98).[18] Although in our study more women required intermittent self-catheterization in the TVT group, this did not represent a significant difference. All cases were treated with clean intermittent self-catheterization and difficult voiding resolved in all without tape division. The incidence of new or worsening overactive bladder symptoms was equivalent between the TVT and TVT-O groups in our study (5.1% and 11.3%, respectively, $p = 0.30$). This is consistent with other data showing no difference in overactive symptoms.[18]

Leg/groin pain was experienced by 26.4% of women in the TVT-O group but by only 1 (1.7%) in the TVT group. In this patient chronic pain developed that persisted 6 months after surgery. She was referred to the chronic pain team. There was sufficient response to amitriptyline and gabapentin, which obviated the need for tape removal. In all other cases of leg pain in the TVT-O group the problem resolved spontaneously within 3 months. In the study by Lim et al of 100 TVT-O procedures 24.4% of women experienced groin discomfort within the first 6 months postoperatively.[17] Of these women 3.6% had persistent groin pain that had not resolved by 1 year, requiring eventual surgery. Groin pain was also more commonly reported in the TVT-O group by Laurikainen et al (1.5 vs 16%, $p < 0.001$) and it seemed to last longer.[24] A recent systematic review also showed a higher incidence of postoperative groin pain after transobturator compared with retropubic tapes.[18]

We stopped our study early based on this growing evidence of equal efficacy for either procedure but a significantly increased incidence of postoperative leg pain after transobturator insertion. Nevertheless, our data will be useful for future meta-analyses and systematic reviews. This problem may be peculiar to the inside out and not the outside in technique since studies comparing TVT with outside in tapes do not indicate a higher incidence of leg pain in the transobturator group.[25] In the systematic review by Lat-

Table 4. *Changes in outcome measures 6 months and 1 year after surgery*

	No. Pts	Median Preop (range)	No. Pts	Median Postop (range)	p Value (Wilcoxon signed ranks test)
			TVT		
6 Mos:					
KHQ	59	383 (122–814)	57	58 (0–647)	0.0001
ICIQ-SF	58	14 (7–21)	57	1 (0–18)	0.0001
Pad loss	59	32 (1–513)	59	1 (0–84)	0.0001
1 Yr:					
KHQ	59	383 (122–814)	37	50 (0–510)	0.0002
ICIQ-SF	58	14 (7–21)	37	4 (0–16)	0.0004
Pad loss	59	32 (1–513)	40	1.8 (0–90.8)	0.0001
			TVT-O		
6 Mos:					
KHQ	49	397 (106–814)	49	58 (0–825)	0.0003
ICIQ-SF	50	14 (3–21)	47	0 (0–20)	0.0007
Pad loss	53	25 (1–271)	53	1.5 (0–135)	0.0002
1 Yr:					
KHQ	49	397 (106–814)	27	61 (0–748)	0.0006
ICIQ-SF	50	14 (3–21)	27	0 (0–11)	0.0006
Pad loss	53	25 (1–271)	29	0 (0–142)	0.0002

the et al subgroup analysis of the transobturator tape group demonstrated that the incidence of groin pain was significantly higher in the inside out than in the outside in group (OR 8.8, CI 2.6–29.5 vs 5.2, CI 0.25–111.2).[18] Cadaveric studies have revealed that the tape passes much closer to the obturator nerve using the inside out than the outside in technique.[26,27] This could possibly cause the obturator nerve to be more susceptible to damage, inflammation and edema, resulting in pain. Neuropathy resulting in gait abnormality and numbness has also been reported and seems to be associated more with the inside out technique.[28]

CONCLUSIONS

Short-term cure rates at 6 months are similar for the 2 procedures. TVT-O results in a higher level of postoperative and leg pain, although these problems are transient. Our findings are similar to those in other studies comparing retropubic and transobturator tapes. The 2 procedures have a high cure rate with a low rate of complications.

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